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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,979	03/24/2004	Assaf Govari	BIO-5044	4469
27777	7590	11/19/2007	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			VRETTAKOS, PETER J	
			ART UNIT	PAPER NUMBER
			3739	
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			11/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/807,979

Applicant(s)

GOVARI, ASSAF

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The application is published application number: 2005/0215 990. The publication is classified in US 606/27.

The effective filing date of this application is 3-24-04.

Pending claims are 1 and 4-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sliwa (6,971,394) in view of Shturman (5,331,947).

Sliwa discloses numerous embodiments including a catheter with ablation devices (see figures 5a-c, 12-13, 14a). It is noted that Sliwa discloses that ablation devices can be electrodes or ultrasonic transducers (col. 3:7-14). Therefore, disclosed embodiments with electrodes are tantamount to disclosing the same embodiment but with ultrasound transducers.

In another embodiment including an ablation device (see figure 64) Sliwa discloses:

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1. Apparatus (see figure 64, *inter alia*) for use with a subject, comprising: a catheter (see figure 8, *inter alia*) having a longitudinal axis and having a distal portion; and an ultrasound array (406) fixed to the distal portion, adapted to operate in a phased array mode (col. 29:26-30) to apply ablating energy to tissue of the subject. **Further**, Sliwa discloses an apparatus wherein an ultrasound array is adapted to apply the ablating energy to tissue in a range of azimuths between about 180 and 359 degrees (Sliwa discloses an apparatus for forming a **continuous lesion around the circular pulmonary vein** – see col. 3:10-15).

4. The apparatus according to claim 1, wherein when the catheter is disposed in a vicinity of an ostium of a pulmonary vein (col. 2:57-60, *inter alia*) of the subject, the range of azimuths is sufficiently smaller than 360 degrees to avoid inducing a deficit in a phrenic nerve (col. 17:25-30; col. 2:22) of the subject.

5. The apparatus according to claim 1, comprising detection functionality (imaging disclosed in col. 3:53-57, col. 16:30-33, col. 16:53-56, and col. 34:51), adapted to determine tissue of the subject that is not to be targeted by the ablating energy (visualization / imaging certainly does this), wherein the ultrasound array is adapted to (control system 334; col. 34:45-57) configure the ablating energy responsive to the determination of the tissue that is not to be targeted.

6. The apparatus according to claim 5, wherein the ultrasound array is adapted

to (control system 334, col. 34:45-57) set the range of azimuths responsive to the determination of the tissue that is not to be targeted.

7. The apparatus according to claim 5, wherein the detection functionality comprises an ultrasound transducer ("ultrasound probes" is synonymous to ultrasound transducer – see col. 16:54).

8. The apparatus according to claim 5, wherein the detection functionality comprises at least a portion of the ultrasound array ("ultrasound probes" is synonymous to ultrasound array – see col. 16:54).

9. The apparatus according to claim 5, wherein the detection functionality comprises imaging functionality (imaging disclosed in col. 3:53-57, col. 16:30-33, col. 16:53-56, and col. 34:51).

Sliwa discloses more than one transducer. See col. 7:15-17, *inter alia*.

Sliwa is silent regarding azimuths and transducer numbers between 32 and 64.

However, Shturman (5,331,947) discloses 32 and 64 transducers in an analogous catheter (note the similarities in catheter 20 in Shturman figures 7, 8, 9, 10, 11, 12, and 13 to those in Sliwa figures 5a-c, 12-13, 14a). Remember, the electrodes

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in Sliwa embodiments can seamlessly be exchanged for ultrasound transducers (Sliwa col. 3:7-10). See Shturman col. 6:47-52 where the number of transducers is suggestively 32 or 64 also known as “binary” numbers. The transducers are suggestively placed circumferentially, therefore capable of ablating between 180 and 359 degrees around the catheter.

Therefore, it would have been obvious at the time of the invention to modify Sliwa in view of Shturman by circumferentially placing 32 or 64 ultrasound transducers as done in Shturman on a Sliwa embodiment from figures 5a-c, 12-13, 14a. The motivation to include into the Sliwa embodiments 32 or 64 circumferentially placed transducers is to use a well-known strategy in ultrasound signal processing (binary number signal processing) and to be able to ablate all tissue surrounding the catheter (as suggested in the pulmonary vein treatment disclosed in Sliwa col. 3:10-15.)

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sliwa (6,971,394) in view of Shturman (5,331,947) and further in view of Crowley et al. (6,004,269).

Sliwa/Shturman is silent regarding imaging transducers being adjacent to ablation transducers (making the image transducer part of the array) at the distal portion of the catheter and an external imaging transducer/detection functionality.

Crowley discloses an analogous ultrasound catheter in which imaging transducers (416) are adjacent to ablation transducers (414) at the distal portion of the

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catheter. See figure 32a. Crowley also discloses an external visualizing ultrasound device in col. 29:35-37. The motivation to combine the patents is to better define what is suggested in Sliwa (the suggestion of ultrasound imaging) as well as to provide a specific means to visualize the targeted and non-targeted tissue.

Therefore, at the time of the invention in would have been obvious to one of ordinary skill in the art to modify Sliwa in view of Shturman and further in view of Crowley by using an external visualizing ultrasound device or an internal ultrasound transducer for visualizing at the distal tip of the catheter. Again, the motivation to combine the patents is to better define what is suggested in Sliwa/Shturman as well as to provide a specific means to visualize the targeted and non-targeted tissue. Sliwa suggests imaging as well as using transducers for purposes other than ablation in col. 3:53-57, col. 16:30-33, col. 16:53-56, col. 34:51, and col. 7:25-27.

Response to Arguments

Applicant's arguments filed 9-21-07 have been fully considered but they are not persuasive. Sliwa discloses a catheter with multiple ultrasound transducers capable of forming uninterrupted circumferential lesions around the pulmonary vein (col. 3:7-14). Inherent to a circumferentially designed device with ultrasound transducers arranged all around are azimuths ranging from 0 to 360 degrees. In a catheter analogous to Sliwa, Shturman discloses 32 and 64 transducers. The arranged 32 and 64 transducers around the circumferential end of the Sliwa device, one makes obvious the Applicant's

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invention notwithstanding threading through the venous system (intended use) and avoiding inducing deficit in a phrenic nerve (discovery not patentable; MPEP § 2112 I.).

The Applicant argues against Crowley. In response, mapping electrodes in Crowley provide external detection functionality because are the electrodes attached to wires that run to an external controller exhibiting detection functionality.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

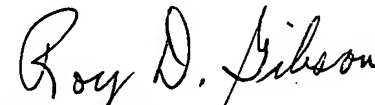
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
November 13, 2007




ROY D. GIBSON
PRIMARY EXAMINER